

5. 510(k) Summary K083920, page 1 of 2

Sponsor: VasoNova Inc.
1368 Bordeaux Drive
Sunnyvale, CA 94089

MAY - 1 2009

Contact Person: Kim Tompkins
Phone Number: 408.738.7006
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Prepared: March 27, 2009

Trade Name: VPS™ Catheter, sizes 3F and 4F name subject to change
Common Name: Central venous catheter
Classification Name: Percutaneous, implanted, long-term intravascular catheter
Classification: II
Product Code: LJS 21 CFR 880.5970
Advisory Panel: General Hospital

Predicate Device: VasoNova VPS Catheter
Bard PerQCath

Device Description

The VPS Catheter and VPS Stylet are designed for use together and with the VPS Console. The VPS Catheter is preloaded with the Stylet and supplied in a tray. The VPS Catheter/Stylet is sterile, single use, non-pyrogenic and non-toxic.

The VPS Catheters are single lumen (3 and 4 Fr) or dual lumen (5 Fr) central venous access catheters made from soft, radiopaque medical grade polyurethane and packaged with the VPS Stylet in a tray with the accessories necessary for a percutaneous micro-introducer placement (Modified Seldinger or Seldinger technique). The VPS Catheters feature a reverse-taper open ended design with a working length of 50 or 55 cm. VPS Catheters are marked at 1 cm intervals and labeled every 5 cm for the entire length.

The VPS Stylet is a 6 foot long polymeric tube which contains a Doppler sensor at the distal tip and an intravascular electrocardiogram (ivECG) signal sensing wire. The Doppler sensor and the ivECG signal sensing wire, when connected to the VPS Stylet are used to detect and transmit physiological information to the VPS Console (available separately). The VPS Stylet has an outer diameter of 0.019 inches and is designed to be used with the compatible VPS Catheter with an inner lumen of 0.021 inches.

Intended Use

VPS catheters are indicated for short or long-term central or peripheral access to the central venous system for intravenous therapy, power injection of contrast media, central venous monitoring and blood sampling.

Performance Data

In vitro testing demonstrates that the subject device meets all acceptance criteria.

Completed testing included:

- Static, burst and dynamic pressure
- Physical characteristics
- Flexural fatigue and flexibility
- Flow rate
- Flexural fatigue, flexibility, collapsibility and elongation
- Tensile and torque strength
- Freedom from air leakage
- Priming volume
- Mechanical hemolysis

Substantial Equivalence

VasoNova VPS Catheters have the same intended use, technological characteristics and principles of operation as its predicate devices. The subject and predicate catheters are similar in that they are fabricated from polyurethane, are 50-55cm in length, have markings every 1-5 cm, have one or two lumens, may have labeled power injectability, and similar flow rates and maximum pressures. Performance data demonstrate that the subject device is as safe and effective as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 1 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim Tompkins, RN, MBA
VP, Regulatory/Quality/Clinical
VasoNova Incorporated
1368 Bordeaux Drive, Suite 100
Sunnyvale, California 94089

Re: K083920

Trade/Device Name: VasoNova VSP Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 27, 2009
Received: April 29, 2009

Dear Ms. Tompkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner".

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. 510(k) Indications for Use

510(k) Number (if known): K083920

Device Name: VasoNova VPS Catheter

Indications for use:

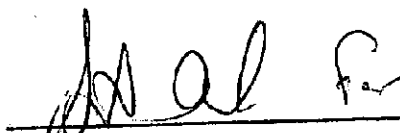
VPS Catheters are indicated for short or long-term peripheral access to the central venous system for intravenous therapy and injection of contrast media. For blood sampling, infusions, or therapies, use a 4F or larger catheter. The maximum recommended injection rate is 2cc/sec for the 3F catheter and 5cc/sec for the 4F and 5F catheters. The VPS Catheter is indicated for use by itself or with the VPS System (Stylet and Console) sold separately.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083920